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EXAMINER	
FETZNER, TIFFANY A	

ART UNIT	PAPER NUMBER
2859	

DATE MAILED: 10/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,527	MCGEE ET AL.	
	Examiner	Art Unit	
	Tiffany A Fetzner	2859	

-- Th MAILING DATE of this communication appears on th cov r sheet with the correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *29 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12/10/2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED Final ACTION

Response to arguments

1. Applicant argues on page 7 of the July 16th 2003 faxed amendment that claim 1 has been amended to call for employing the phase difference image to locate an implant in the subject and states that the **Bernstein** reference is an MRA method and implants are not even seen in such images. Additionally, applicant argues that there is no recognition anywhere in **Berstein** that the phase difference data can be used to locate implants. [See page 7 of the July 16th 2003 faxed amendment, where the arguments to distinguish over the prior art are made.] The other main argument raised by applicant is that the combination of **Bernstein** and **Zhang et al.**, (i.e. the **Zhang et al** reference US patent 6,332,088 B1,does deal with the problem of imaging inanimate objects, (i.e. stationary implants or devices) in a subject), is improper because "there is no recognition in either of these references that a phase difference image from two data sets acquired with two different pulse sequences can be used to locate implants" [See page 7 last paragraph of the July 16th 2003 faxed amendment, where the arguments to distinguish over the prior art are made.]

2. In response to these arguments the examiner notes that additional art addressing applicant's amended limitations of July 16th and July 29th 2003 has been found, which specifically shows and directly suggests from the figures, and abstract that "a phase difference image from two data sets acquired with two different pulse sequences can be used to locate implants". [See the abstract and figures of the **Frankel et al.**, article "Characteristics of magnetic resonance sequences used for imaging silicone gel, saline,

and gel-saline implants at low field strengths." **Frankel** S; **Occhipinti** K; **Kaufman** L; **Kramer** D; **Carlson** J; **Mineyev** M; **Friedenthal** R Investigative radiology (UNITED STATES) **Aug 1994**, 29 (8) p781-6, ISSN 0020-9996 Journal Code: 0045377.

3. The examiner is also **not persuaded** by applicant's argument that an MRA technique is not combinable with an MR method designed to locate a stationary implant or device because the MR images of **Frankel et al.**, clearly show that MR images which locate a stationary implant, also show flowing fluid in the imaged area.

4. Applicant's arguments with respect to **claims 1-4**, and **6-19** have been considered but are moot in view of the new ground(s) of rejection, necessitated by applicant's amendments of July 16th 2003 and July 29th 2003. The new references applied are **Frankel et al.**, **the Moerland et al.**, article. (i.e. article by **Moerland** M A; **Wijrdeman** H K; **Beersma** R; **Bakker** C J; **Battermann** J J International journal of radiation oncology, biology, physics (UNITED STATES) **Mar 1 1997**, 37 (4) p927-33, ISSN 0360-3016 Journal Code: 7603616); and the **Tominaga et al.,** article (i.e. "Magnetic resonance imaging of titanium anterior cervical spine plating systems" **Tominaga** T.; Shimizu H.; Koshu K.; Kayama T.; Yoshimoto T.; Cooper P.R.;Sonntag V.K.H. Neurosurgery (NEUROSURGERY) (United States) **1995**, 36/5 (951-955) CODEN: NRSRD ISSN: 0148-396X).

Canceled claims

5. **Claim 5 is canceled** as per applicant's July 16th 2003 amendment response.

Claim objections

6. **Amended Claim 8** is objected to because of the following informalities:

Amended claim 8 step e) sates "employing the phase difference MR image to display the location of the an implant in the magnitude MR image **to** form the image." The phrase to form the image is awkward, the examiner suggests that the word "to" be replaced by the word "and". Appropriate correction is required.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. **Claims 1-4, 6, 8-12, 15,** and **19** are rejected under **35 U.S.C. 103(a)** as being unpatentable over **Bernstein et al.**, US patent 5,226,418; in view of the article "Characteristics of magnetic resonance sequences used for imaging silicone gel, saline, and gel-saline implants at low field strengths." **Frankel** S; **Occhipinti** K; **Kaufman** L; **Kramer** D; **Carlson** J; **Mineyev** M; **Friedenthal** R Investigative radiology (UNITED STATES) **Aug 1994**, 29 (8) p781-6, ISSN 0020-9996 Journal Code: 0045377. Here after the **Frankel et al.**, article.

11. With respect to **Amended Claim 1**, **Bernstein et al.**, teaches "A method for producing an image of a subject with a magnetic resonance imaging (MRI)" / nuclear magnetic resonance (NMR) "system", [See **Bernstein et al.,** col. 1 lines 7-12] **Bernstein et al.**, also teaches and suggests "the steps comprising **a)** acquiring a first k-space data set with the MRI / NMR system using a first pulse sequence;" [See col. 4 line 67 through col. 5 line 16; col. 9 lines 26-44] " **b)** acquiring a second k-space data set with the MRI / NMR system using a second pulse sequence which is different from the first pulse sequence;" [See col. 4 line 67 through col. 5 line 16; col. 9 lines 26-44] "**c)** reconstructing first and second complex MR images of the subject from the respective first and second k-space data sets;" [See col. 9 lines 45-59; col. 10 lines 32-63; col. 11 lines 7-32;] "**d)** calculating a phase difference MR image from the first and second complex MR images;" [See col. 11 line 33 through col. 12 line 61] "**e)** calculating

a magnitude MR image from one of said first or second complex MR images;" [See col. 12 line 43-66; Figure 4].

12. **Bernstein et al.**, lacks directly teaching that the "magnetic resonance imaging (MRI) system, enables a previously implanted device to be located", that each of the pulse sequences used in steps **a)** and **b)** are suitable for imaging stationary spins;" and newly added amended steps " f) employing the phase difference MR image to locate the implant in the subject; and g) displaying the location of the implant in the magnitude MR image." However, each of these amended features are taught, shown and / or suggested in the **Frankel et al.**, article, because **Frankel et al.**, teaches suggests and shows "A method for producing an image of a subject with a magnetic resonance imaging (MRI) system, which enables a previously implanted device to be located," [See abstract Methods on page 781 and figures 1-4 on pages 784 and 785] "the steps comprising **a)** acquiring a first k-space data set with the MRI system using a first pulse sequence suitable for imaging stationary spins;" and "**b)** acquiring a second k-space data set with the MRI system using a second pulse sequence suitable for imaging stationary spins which is different from the first pulse sequence;" [See abstract rationale and objectives, on page 781; the "Sequences" section on page 782-783 and figures 1-4 on pages 784 and 785. The examiner notes that because the stationary implant is located in the MR images of figure 1-4 that the imaging sequences are "suitable for imaging stationary spins" as required by applicant's July 7th 2003, and July 29th 2003 amendments. Additionally the data matrices taught in the "Sequences" section on page 782-783, are interpreted as k-space data sets, because in MRI the matrices used, are k-

space data sets, prior to the required Fourier Transformation and image reconstruction steps used to produce, MRI phase and magnitude images, such as the ones shown in Figures 1 through 4. The examiner interprets the individual matrices for each type of sequence as a first and second 'k-space" data set].

13. **Frankel et al.**, also teaches suggests and shows the newly added amended steps of " f) employing the phase difference MR image to locate the implant in the subject; and g) displaying the location of the implant in the magnitude MR image." [See **Frankel et al.**, abstract rationale and objectives, methods, results and conclusions section on page 781, where phase images are used to differentiate protons in stationary silicone, water and fat in MR breast images; the "Sequences" section on page 782-783 and figures 1-4 on pages 784 and 785; especially the captions of figure 2, where the top MR magnitude image was made from a GRE sequence the center MR magnitude image was made from sequence 2 (i.e. a spin-echo IR sequence), and the bottom MR image is the phase MR image which confirms the findings of the GRE magnitude image.] The implants and the tissue around the implant are visible, in **Frankel et al.**, Figures 1-4 which include magnitude and phase images.

14. It would have been obvious to one of ordinary skill in the art at the time that the invention was made to modify the teaching of **Bernstein et al.**, with the teachings of the **Frankel et al.**, article because both references image fluids that move within the living tissues of a patient, (i.e. **Bernstein et al.**, images blood flow to produce MR angiograms within a patient's tissues; while **Frankel et al.**, images an implanted device, along with the tissue and fluids around the implant, [See Figure 1 page 784 where tissue, fluid f,

and saline implant SA are shown]), and the images of the **Frankel et al.**, article show that flowing fluids are detectable, in MR techniques designed to image saline implants. [See Figure 1 page 784 where tissue, fluid f, and saline implant SA are shown] Additionally, the examiner notes that a saline implant is in itself a fluidic device, the saline solution within the confines of the implant does move, therefore it would have been readily obvious to one of ordinary skill in the art at the time that the invention was made, that MR methods to measure flowing liquids in the body, would also be available for imaging flowing fluid in tissues, and implanted devices within or around flowing fluids. The **Frankel et al.**, article images silicone-gel; saline, and gel-saline implant combinations, therefore It would have been obvious to one of ordinary skill in the art at the time that the invention was made to modify MR techniques designed to image stationary objects, flowing fluid, or combinations of each, (i.e. patient tissues), with the teachings of **Frankel et al.**, to include the imaging of implants in MR magnitude and phase images.

15. With respect to **Claim 2**, **Bernstein et al.,** teaches "said first pulse sequence is a spin-echo pulse sequence in which an NMR echo signal is produced after an RF refocusing pulse is produced, [See col. 2 line 52 through col. 3 lines 1-7; col. 10 lines 45-50] **Bernstein et al.**, teaches and suggests that "the second pulse sequence is a gradient-recalled echo pulse sequence in which an NMR echo signal is produced after an RF excitation pulse is produced." [See col. 9 lines 15-25; col. 8 lines 55-60] Additionally, **Frankel et al.**, also teaches this limitation. [See **Frankel et al.**, abstract rationale and objectives on page 782; and the Sequences section of pages 782-783;

Figures 1-4] The same reasons for rejection, obviousness, and motivation to combine, that apply to **claim 1** also apply to **claim 2**.

16. With respect to **Claim 3**, **Bernstein et al.**, teaches and shows "step **c)** is performed by performing a complex Fourier transformation of each of the first and second k-space data sets." [See col. 11 lines 7-32; Figure 4]. Additionally, the Fourier transformation of each sequence to produce an image is also taught by **Frankel et al.** [See the captions of Figures 1 through 4 pages 784-785] The same reasons for rejection, obviousness, and motivation to combine, that apply to **claim 1** also apply to **claim 3**.

17. With respect to **Claim 4**, **Bernstein et al.**, teaches and shows "step **d)** is performed by: **i)** calculating a first phase image from the first complex image; **ii)** calculating a second phase image from the second complex image; **iii)** calculating the phase difference image by computing the phase difference between corresponding pixels in the first and second phase images." [See col. 9 line 7 through col. 13 line 15; Figure 4] The same reasons for rejection, obviousness, and motivation to combine, that apply to **claim 1** also apply to **claim 4**.

18. With respect to **Claim 6**, **Bernstein et al.**, lacks directly teaching that "the subject is tissues containing an implant". However **Frankel et al.**, shows that the subject is human female breast tissues "containing an implant". [See Figures 1 through 4 pages 784-785; and the teachings of pages 781-786 in general] The same reasons for rejection, obviousness, and motivation to combine, that apply to **claim 1** also apply to **claim 6**.

19. With respect to **claim 8**, which is another version of **claim 1**, which incorporates the limitations of **claim 2**, and specifically requires that the MR images are "images are of tissues containing an implant". The teachings of what **Bernstein et al.**, teaches and lacks in **amended claim 1**, also apply to **amended claim 8** and need not be reiterated.

20. **Bernstein et al.**, lacks teaching that "the images are of tissues containing an implant". However, as mentioned in the rejection of **claim 1**, **Frankel et al.**, shows that the MR images are of tissues containing an implant" subject is human female breast tissues "containing an implant". [See Figures 1 through 4 pages 784-785; and the results section of pages 783-786.] **Bernstein et al.**, also lacks teaching step **e)** of "employing the phase difference MR image to display the location of the an implant in the magnitude MR image" *and* "form the image." However, this limitation was already addressed in the rejection of **amended claim 1**, which need not be reiterated. The same reasons for rejection, obviousness, and motivation to combine, that apply to **claims 1, 2** also apply to **amended claim 8**.

21. With respect to **Claim 9, Bernstein et al.,** teaches and suggests that "step b) is performed by performing a complex Fourier transformation of each of the first and second k-space data sets." [See col. 11 lines 7-32; Figure 4]. The same reasons for rejection, obviousness, and motivation to combine, that apply to **amended claims 1, 2, 8** also apply to **amended claim 9**.

22. With respect to **Claim 10**, **Bernstein et al.,** teaches that "step a) is performed by: I) performing a first pulse sequence to acquire the NMR spin-echo signals; and ii) performing a different pulse sequence to acquire the NMR gradient-recalled signals.

[See col. 2 line 52 through col. 3 lines 1-7; col. 10 lines 45-50; col. 9 lines 15-25; col. 8 lines 55-60]. The same reasons for rejection, obviousness, and motivation to combine, that apply to **amended claims 1, 2, 8** also apply to **amended claim 9**.

23. With respect to **Claim 11**, **Bernstein et al.,** teaches that at least "one NMR signal is acquired with each pulse sequence", [See col. 2 line 52 through col. 3 lines 1-7; col. 10 lines 45-50; col. 9 lines 15-25; col. 8 lines 55-60]. The same reasons for rejection, obviousness, and motivation to combine, that apply to **amended claims 1, 2, 8, 10** also apply to **amended claim 11**.

24. With respect to **Claim 12, Bernstein et al.,** teaches the limitations that "step **c)** is performed by: i) calculating a first phase image from the first complex image; ii) calculating a second phase image from the second complex image; iii) calculating the phase difference image by computing the phase difference between corresponding pixels in the first and second phase images", [See col 9 line 7 through col. 13 line 15; Figure 4]. The same reasons for rejection, obviousness, and motivation to combine, that apply to **amended claims 1, 2, 8** also apply to **amended claim 12**.

25. With respect to **Amended claim 15**, which is another version of **claim 1**, which specifically requires that the MR images are "images are of tissues containing an implant", and requires the features of dependent claim 3; **Bernstein et al.**, teaches "A method for producing an image of a subject with a magnetic resonance imaging (MRI)" / nuclear magnetic resonance (NMR) "system", [See **Bernstein et al.,** col. 1 lines 7-12] **Bernstein et al.**, also teaches and suggests "the steps comprising **a)** acquiring a complex k-space data set with the MRI / NMR system using a pulse sequence;" [See

col. 4 line 67 through col. 5 line 16; col. 9 lines 26-44] "**b)** reconstructing a complex MR image by Fourier transforming the complex k-space data set;" [See col. 11 lines 7-32; col. 9 lines 45-59; col. 10 lines 32-63; col. 11 lines 7-32 Figure 4]. Additionally, the Fourier transformation of each sequence to produce an image is also taught by **Frankel et al.** [See the captions of Figures 1 through 4 pages 784-785]

26. **Bernstein et al.**, lacks teaching that "the images are of tissues containing an implant". However, as mentioned in the rejection of **claim 1**, **Frankel et al.**, shows that the MR images are of tissues containing an implant" subject is human female breast tissues "containing an implant". [See Figures 1 through 4 pages 784-785; and the results section of pages 783-786.] **Bernstein et al.**, also lacks teaching steps "; **c)** calculating a phase MR image from the complex MR image which differentiates between the implant and the surrounding tissues; **d)** calculating a magnitude image from the complex image which differentiates between tissues; **e)** locating the implant in the tissues using information in the phase MR image; and **f)** displaying the location of the implant in the magnitude MR image." However, **Frankel et al.**, teaches and shows the step of calculating a phase MR image from the complex MR image which differentiates between the implant and the surrounding tissues; [See **Frankel et al.**, abstract rationale and objectives, methods, results and conclusions section on page 781, where phase images are used to differentiate protons in stationary silicone, water and fat in MR breast images; the "Sequences" section on page 782-783 and figures 1-4 on pages 784 and 785; especially the captions of figure 1, where tissue, fluid, and the

silicone implant are shown to be differentiated, and the bottom figure of figure 2 which shows a phase image specifically.]

27. **Frankel et al.**, also teaches suggests and shows step **"d)** calculating a magnitude image from the complex image which differentiates between tissues; [See **Frankel et al.**, abstract rationale and objectives, methods, results and conclusions section on page 781, where phase images are used to differentiate protons in stationary silicone, water and fat in MR breast images; the "Sequences" section on page 782-783 and figures 1-4 on pages 784 and 785; especially the captions of figure 2, where the top MR magnitude image was made from a GRE sequence the center MR magnitude image was made from sequence 2 (i.e. a spin-echo IR sequence), and the bottom MR image is the phase MR image which confirms the findings of the GRE magnitude image.] Additionally, **Frankel et al.**, teaches suggests and shows step **e)** locating the implant in the tissues using information in the phase MR image; and **f)** displaying the location of the implant in the magnitude MR image." [See **Frankel et al.**, abstract rationale and objectives, methods, results and conclusions section on page 781, where phase images are used to differentiate protons in stationary silicone, water and fat in MR breast images; the "Sequences" section on page 782-783 and figures 1-4 on pages 784 and 785; especially the captions of figure 2, where the top MR magnitude image was made from a GRE sequence the center MR magnitude image was made from sequence 2 (i.e. a spin-echo IR sequence), and the bottom MR image is the phase MR image which confirms the findings of the GRE magnitude image.] The implants and the tissue around the implant are visible, in **Frankel et al.**, Figures 1-4 which include

magnitude and phase images. The same reasons for rejection, obviousness, and motivation to combine, that apply to **amended claims 1, 3, 8, 9, 10, 11** also apply to **amended claim 15** and need not be reiterated .

28. With respect to **Amended claim 19**, which is another version of **claim 1**, which specifically requires that the MR images are "images are of tissues containing an implant", and also requires that the system differentiates between soft tissues and which differentiates between tissues and a device; The teachings of what **Bernstein et al.**, teaches and lacks in **amended claims 1, 8,** and **15**, also apply to **amended claim 19** and need not be reiterated therefore limitations of steps **a)** acquiring a first k-space data set with the MRI system using a first pulse sequence; **b)** acquiring a second k-space data set with the MRI system using a gradient-recalled echo pulse sequence; **c)** reconstructing first and second complex MR images of the subject from the respective first and second k-space data sets; **d)** calculating a phase difference MR image from the first and second complex images, **e)** calculating a magnitude MR image from one of said first or second complex MR images, and **f)** combining the phase difference MR image with the magnitude MR image to form the image of the subject", are considered by the examiner to have already been addressed in this action.

29. With respect to the **amended** features of **claim 19** in steps **d)** where the phase difference MR image differentiates between tissues and a device and **e)** where the magnitude image differentiates between tissues the examiner notes that **Bernstein et al.**, lacks these features but **Frankel et al.**, teaches, shows and suggests the differentiation between tissues and an implanted device in both phase and magnitude

images. [See **Frankel et al.**, abstract rationale and objectives, methods, results and conclusions section on page 781, where phase images are used to differentiate protons in stationary silicone, water and fat in MR breast images; the "Sequences" section on page 782-783 and figures 1-4 on pages 784 and 785; especially the captions of figure 2, where the top MR magnitude image was made from a GRE sequence the center MR magnitude image was made from sequence 2 (i.e. a spin-echo IR sequence), and the bottom MR image is the phase MR image which confirms the findings of the GRE magnitude image; and Figure 1 where tissue, fluid and the implanted device are located and visible..] The implants and the tissue around the implant are visible, in **Frankel et al.**, Figures 1-4 which include magnitude and phase images. The same reasons for rejection, obviousness, and motivation to combine, that apply to **amended claims 1, 2, 3, 8, 9, 10, 11, 15** also apply to **amended claim 19** and need not be reiterated .

30. **Claims 7, 13,** and **18** are rejected under **35 U.S.C. 103(a)** as being unpatentable over **Bernstein et al.**, US patent 5,226,418; and the **Frankel et al.,** article "Characteristics of magnetic resonance sequences used for imaging silicone gel, saline, and gel-saline implants at low field strengths"; Investigative radiology (UNITED STATES) **Aug 1994**, 29 (8) p781-6, ISSN 0020-9996 Journal Code: 0045377; as applied to **amended claims 1-4, 6, 8-12** and **15** above, in further view of alternatively, **Slater et al.,** US patent 6,200,258 B1 or the **Moerland et al.**, article. (i.e. article by **Moerland** M A; **Wijrdeman** H K; **Beersma** R; **Bakker** C J; **Battermann** J J International journal of radiation oncology, biology, physics (UNITED STATES) **Mar 1 1997**, 37 (4) p927-33, ISSN 0360-3016 Journal Code: 7603616).

31. With respect to **corresponding claims 7, 13,** and **18,** which depend respectively from amended independent **claims 1, 8,** and **15**; Both **Bernstein et al.,** and the **Frankel et al**., article lack teaching that "the tissues include a human prostate and the implant is a brachytherapy seed". However, the **Moerland et al**., article specifically teaches an MR method for imaging a human prostate where the implant is a brachytherapy seed". [See pages 927 through 922 as the MR imaging of a human prostate in which I-125 seeds have been planted, is explained in numerous detail throughout the article and figures.] The examiner notes that the I-125 seeds of **Moerland et al**., are a conventionally well known, and commonly used type of "brachytherapy" seed.

32. Additionally or alternatively, **Slater et al.,** teaches the limitation that "the MRI subject is prostate tissues containing a brachytherapy seed implant" [See **Slater et al**., col. 1 lines 13-30; col. 1 line 67 through col. 2 line 2; col. 4 line 64 through col. 5 line 21, where a titanium brachytherapy seed implant is implanted in tissues in the successful treatment of various types of cancers including prostate cancer.] The examiner also notes that **Slater et al.,** also teaches that "radioactive therapeutic seeds" (i.e. the I-125 seeds of **Moerland et al**., are "radioactive therapeutic seeds"), have been in use for over thirty years" [See **Slater et al.,** col. 2 lines 31-32]. It would have been obvious to one of ordinary skill in the art at the time that the invention was made to modify the teachings of **Bernstein et al., and Frankel et al**., with the teachings of either **Moerland et al**., or **Slater et al.,** when the desired region to be imaged is the human prostate because different areas of the body conventionally have different kinds of

implants, and brachytherapy seeds are conventionally associated with prostation implants. The same reasons for rejection, obviousness, and motivation to combine, that apply to **amended claims 1, 2, 6, 8, 15** also apply to **claims 7, 13,** and **18.**

33. **Claim 14** is rejected under **35 U.S.C. 103(a)** as being unpatentable over **Bernstein et al.,** US patent 5,226,418; in view of the **Frankel et al.,** article "Characteristics of magnetic resonance sequences used for imaging silicone gel, saline, and gel-saline implants at low field strengths"; Investigative radiology (UNITED STATES) **Aug 1994**, 29 (8) p781-6, ISSN 0020-9996 Journal Code: 0045377; as applied to **amended claims 1-4, 6, 7, 8-12, 13, 15** and **18** above, in further view of alternatively, **Slater et al.,** US patent 6,200,258 B1; or the **Moerland et al.**, article. (i.e. article by **Moerland** M A; **Wijrdeman** H K; **Beersma** R; **Bakker** C J; **Battermann** J J International journal of radiation oncology, biology, physics (UNITED STATES) **Mar 1 1997**, 37 (4) p927-33, ISSN 0360-3016 Journal Code: 7603616); or the and further in view of alternatively **Slater et al.,** US patent 6,200,258 B1 or the **Tominaga et al.,** article (i.e. "Magnetic resonance imaging of titanium anterior cervical spine plating systems" **Tominaga** T.; Shimizu H.; Koshu K.; Kayama T.; Yoshimoto T.; Cooper P.R.;Sonntag V.K.H. Neurosurgery (NEUROSURGERY) (United States) **1995**, 36/5 (951-955) CODEN: NRSRD ISSN: 0148-396X). Hereafter the **Tominaga et al.,** article.

34. With respect to **Claim 14**, **Bernstein et al.,** and **Frankel et al.**, lack teaching that "the implant is formed of titanium". However, this feature is taught and suggested by both the **Slat r et al.**, and **Tominaga et al.**, references. [See the **Tominaga et al.**, article page 951 col. 1 paragraph 2; page 952 the clinical examinations sections and ex-

vivo phantom experiments; **Slater et al.,** col. 1 line 67 through col. 2 line 2; col. 4 lines 64-67; col. 5 lines 7-10].

35. It would have been obvious to one of ordinary skill in the art, at the time that the invention was made to modify the teachings of **Bernstein et al.,** and **Frankel et al.**, to include imaging of a titanium implant as taught in one of the **Tominaga et al.**, or **Slater et al.,** references because titanium is strong, does not break easily, and is a material from which many conventionally well known interventional medical devices/implants, that are viewable with MRI methods and visible in MRI images, are made. Additionally, the type of implant generally depends on what region of the body is to be imaged. The examiner notes Breast implants in MR methods are conventionally made of silicone; (i.e. **Frankel et al.**,). Prostate implants in MR methods are typically brachtherapy seeds, (i.e. **Moerland et al.**, or **Slater et al.),** Implants for the knee, hip, foot, or cervical spine in MR methods are commonly titanium (i.e. **Tominaga et al.**,). Therefore, It would have been obvious to one of ordinary skill in the art at the time that the invention was made that the material from which an implant is made depends on where in the body the implant is located, but all of the references above are capable of locating the implants in MRI methods. The same reasons for rejection, obviousness, and motivation to combine, that apply to **Amended claims 1, 2, 8, 13,** and **15** also apply to **claim 14**.

36. **Claims 16** and **17** are rejected under **35 U.S.C. 103(a)** as being unpatentable over **Bernstein et al.,** US patent 5,226,418; in view of the **Frankel et al.,** article "Characteristics of magnetic resonance sequences used for imaging silicone gel, saline, and gel-saline implants at low field strengths"; Investigative radiology (UNITED

STATES) **Aug 1994**, 29 (8) p781-6, ISSN 0020-9996 Journal Code: 0045377; as applied to **amended claims 1-4, 6, 7, 8-12, 13, 15** and **18** above, in further view of the **Moerland et al.**, article. (i.e. article by **Moerland** M A; **Wijrdeman** H K; **Beersma** R; **Bakker** C J; **Battermann** J J International journal of radiation oncology, biology, physics (UNITED STATES) **Mar 1 1997**, 37 (4) p927-33, ISSN 0360-3016 Journal Code: 7603616).

37. With respect to **Amended Claims 16** and **17**, **Bernstein et al.,** and **Frankel et al.,** in combination disclose an MRI system/method as stated above with respect to **claims 1, 8, 15,** and **19**, and the teachings of those claims, are considered to have already been addressed by the examiner. Both **Bernstein et al.,** and **Frankel et al.,** lack directly teaching that with respect to **claim 16,** that "step **f)**" depending from amended claim 15 is performed by: "modifying pixels in the magnitude image at the implant location" however, the **Moerland et al.**, article teaches this limitation. [See page 928 through page 932 where the algorithm and process for monitoring and modifying the pixels of the MR imaged prostates is explained, in detail with additional algorithms and modifications also being taught. See also the tables and figures found on pages 928 through 932.]

38. It would have been obvious to one of ordinary skill in the art at the time that the invention was made to modify the teaching of **Bernstein et al.,** and **Frankel et al.,** with the teaching of the **Moerland et al.**, article regarding the MR monitoring of implanted devices in prostate tissues, by pixel modification in the magnitude images because an implantation surgery initially causes the tissue to swell up, and over time return to

normal. MR scans performed following implantation and MR scans performed during a follow-up exam days or months later will have discrepancies due to the reduction in swelling and/or the possible migration of the implanted device(s). Therefore, It would have been readily obvious that MR evaluation methods have a means for "modifying pixels in the magnitude image at the implant location". The same reasons for rejection, obviousness, and motivation to combine, that apply to **amended claims 1, 3, 8, 9, 10, 11, 15** also apply to **amended claim 16** and need not be reiterated .

39. Additionally with respect to **claim 17**, both **Bernstein et al.,** and **Frankel et al.,** lack teaching or showing that "step **f)**" depending from amended claim 15 " is "performed by: overlaying a graphical representation of the implant at the implant location". However, the **Moerland et al.**, article teaches this limitation. [See pages 931-932 Figures 2, 3, 4, and Table 2; page 928 Figure 1 which shows an MR image of the seeds in the prostate as single voxels, and constitutes a graphical overlay.] The same reasons for rejection, obviousness, and motivation to combine, that apply to **amended claims 1, 3, 8, 9, 10, 11, 15,** and **16** also apply to **amended claim 17** and need not be reiterated.

40. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

41. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

42. The **prior art made of record** and not relied upon is considered pertinent to applicant's disclosure.

A) **Darrow et al.**, US patent 5,730,129 which shows another MRI tracking system for locating an interventional device within a patient, superimposed on a graphical display.

B) **Harvey** US patent 6,275,038 B1 which shows additional phase-difference techniques used with MRI.

C) **Sliwa et al.**, US patent 6,368,275 B1 issued April 9th 2002 with an effective date of October 7th 1999.

D) **Zhang et al** reference US patent 6,332,088 B1 issued December 18th 2001 with an effective date of November 12th 1998.

Conclusion

43. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tiffany Fetzner whose telephone number is (703) 305-0430. The examiner can normally be reached on Monday-Thursday from 7:00am to 4:30pm., and on alternate Friday's from 7:00am to 3:30pm.

44. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diego Gutierrez, can be reached on (703) 308-3875. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3432.

45. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0956.

Tiffany A. Fegan

TAF

September 25, 2003

Diego Gutierrez

Supervisory Patent Examiner

Technology Center 2800